IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA : 4:17-CR-00403

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v. : (Judge Brann)

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RAYMOND KRAYNAK : (Filed Electronically)

BRIEF IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY

Relevant Procedural History

On December 20, 2017, an Indictment was filed charging Raymond Kraynak with the unlawful distribution and dispensing of a controlled substance, in violation of 21 U.S.C. § 841(a)(1) (Counts 1 through 12); unlawful distribution and dispensing of a controlled substance resulting in death, in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(C) (Counts 13-17); and maintaining drug-involved premises, in violation of 21 U.S.C. § 856(a)(1) (Count 18 and 19).

Dr. Kraynak practiced medicine in the Mount Carmel and Shamokin areas since 1984 when he graduated from the Philadelphia College of Osteopathic Medicine. He grew up in Mount Carmel and returned there after medical school because of the shortage of doctors in Pennsylvania coal country. During his career, he treated thousands of patients with myriad conditions for more than 33 years.

On January 22, 2020, Dr. Kraynak filed a Request for Notice of Expert Testimony. (Doc#52). On January 24, 2020, the government responded to Dr.

Kraynak's request with the report and opinion of Dr. Stephen M. Thomas. See (Exhibit A, Report of Dr. Thomas, Filed under seal).

In that report Dr. Thomas opines, after reviewing the medical records of patients, that Dr. Kraynak's medical treatment was ".... Not in accordance with the accepted treatment principles within the responsible segment of the medical community." Dr. Thomas express this opinion regarding patients DB, RC, WE, FG, FH, DH, AK, ML, TM, CS, JS, and RW. *See* (Exhibit A, pages 6-13). He further opines that RC, FH, DH, AK, ML, and CS "would not have died" but for the prescription practices of Dr. Kraynak. Dr. Thomas draws these conclusions without proper basis and foundation even though there were no autopsies performed on DH, AK, or ML, who are the alleged victims in counts 14-16 which charge Drug Distribution Resulting in Death.

Legal Standards

I. Expert Testimony – Daubert

Federal Rule of Evidence 702 affords the trial judge broad discretion to admit or exclude expert testimony. Rule 702 provides that a qualified expert may testify in the form of an opinion where:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact at issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is a product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702 (2011). As interpreted and applied in *Daubert v. Merrell Dow Pharm.*, *Inc.*, 509 U.S. 579 (1993), the Supreme Court separated Rule 702 into three basic requirements: (1) the expert must be qualified to provide an opinion; (2) the testimony is "relevant to the task at hand" FED. R. EVID. 702(a); and (3) the testimony "rests on a reliable foundation[.]" FED. R. EVID. 702(b)–(d).

Daubert and its progeny set forth a non-exhaustive list of factors the court may use to assess the reliability of expert testimony: (1) whether the expert's principles and methodology can be or have been tested or is otherwise subject to peer-review; (2) the known or potential error rates for a particular technique; (3) any standards and controls applicable to the science; and (4) the degree of acceptance in the relevant scientific context. Daubert, 509 U.S. at 593–94; see also FED. R. EVID. 702, Advisory Committee Notes to 2000 Amendments ["FED. R. EVID. 702 ACN (2000)"].

Rule 702 articulates additional factors the court may use when making reliability assessments, including whether an expert: (1) testified about conclusions made "independent of litigation"; (2) unjustifiably extrapolated from an accepted premise to an unfounded conclusion"; (3) "adequately accounted for obvious alternative explanations"; (4) "is being as careful as he would be in his regular

professional work"; and (5) can "reach reliable results" in his field of expertise. FED. R. EVID. 702 ACN (2000).

The standards set forth in Rule 702 are flexible, and the trial judge may consider any or all specific factors when making admissibility determinations. *Id.*; *see also Daubert* at 594. In response to a motion to exclude expert testimony on this basis, the proponent must demonstrate admissibility by a preponderance of the evidence. FED. R. EVID. 702 ACN (2000) (citing to *Bourjaily v. United States*, 483 U.S. 171 (1987)): *see also* FED. R. EVID. 104(a).

II. Causation – Burrage

The court must determine whether Dr. Thomas' opinion—that RC, FH, DH, AK, ML, and CS (Counts 13 – 17) would not have died but-for the prescription practices of Dr. Kraynak— is reliable and whether it thereby satisfies the causation requirements set forth in *Burrage v. United States*, 571 U.S. 204 (2014).

Section 841(b)(1)(C) requires the Government prove "death or serious bodily injury <u>results from</u> the use of [the distributed] substance[,]" (21 U.S.C. § 841(b)(1)(C) (emphasis added)), but because the Controlled Substances Act does not define <u>results from</u>, the Supreme Court interpreted this phrase in *Burrage*:

"[W]here use of the drug distributed by the defendant is not an independently sufficient cause of the victim's death or serious bodily injury, a defendant cannot be liable under the penalty enhancement provision of 21 U.S.C. § 841(b)(1)(C) unless such use is a but-for cause of the . . . injury."

Id. at 210–11. The Supreme Court explained that use of the substance is the but-for cause, even when it combines with other factors to produce the result, where the other factors would not have done so alone. The Supreme Court additionally indicated that use of the substance must also be the proximate cause of serious death or bodily injury. Id. at 2010 (citing to 1 W. LaFave, Substantive Criminal Law § 6.4(a), 464–66 (2d ed. 2003) (requiring but-for cause and proximate cause where a crime requires "not merely conduct but also a specified result of conduct").

Argument

I. Dr. Thomas's opinion fails to satisfy the reliability requirements of Federal rule of Evidence 702.

Dr. Thomas' expert opinion fails to meet the requirements of Rule 702 because it is not based on (1) sufficient facts or data; (2) reliable principles and methods; or (3) reliable application of principles and methods. Consequently, his proffered testimony is unreliable and inadmissible.

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¹ To illustrate but-for causation, the Court articulated the following hypothetical: poison is administered to a man debilitated by multiple diseases; these diseases contributed to his death; the poison is a but-for cause of the man's death only if he would have lived without the incremental effect of the poison. *Burrage* at 211.

A. Dr. Thomas's opinion is not based on sufficient facts and/or data

Although Rule 702(b)'s "sufficient facts or data" requirement is assessed using a qualitative rather than quantitative analysis (FED. R. EVID. 702 ACN (2000)), expert testimony cannot be based upon hypotheses, "guesstimations", or unsupported speculations. 33 A Fed Proc. Witnesses §206 (2019). "Sufficiency is a function of the nature and scope of the opinion offered, the quantity of data both available and pertinent to the issue at hand, and what is deemed sufficient by experts in the pertinent field when working outside the courtroom." Wright & Miller, 29 Fed. Prac. & Proceed. Testimony by Expert Witness §6268 (2d ed. 2019).

Dr. Thomas's report sets forth the documents he reviewed to reach his opinion. At the onset, Dr. Thomas makes cursory reference to standards, but he does not explain where, why and how the standards are relevant. Dr. Thomas' opinions seemed to be based mostly on his subjective beliefs about Dr. Kraynak's practice. Dr. Thomas did not examine any patient or take into consideration the coal country patient base or any other local practitioner's experiences. He did not review medical journals, nor did he rely on other physician's opinions that Dr. Kraynak's prescriptions and treatments were not medically necessary and not for a legitimate medical purpose.

Daubert directs the trial court to determine whether the expert's testimony rests on a reliable foundation, is relevant to the task at hand and whether the expert is qualified. A central focus of that inquiry is the expert's methodology and the data offered to support the bottom line opinion and to determine whether that data provides adequate support to make the expert's testimony reliable. Louise-Troche v. Pepsi-Cola of P.R. Bottling Co., 161 F. 3d 77, 81 (1st Cir. 1998). Here the methodology used by Dr. Thomas is questionable. All he did was examine patient records and draw conclusions.

Furthermore, we do not know whether Dr. Thomas' technique is acceptable because he never indicates a methodology or a comparison to Dr. Kraynak's practices against any standard. Dr. Thomas also fails to describe whether his techniques have been subject to appear review and publication. There is no citation to any peer review or peer-reviewed article published in a recognized journal.

Most troubling is the fact that Dr. Thomas has reached conclusions for deaths where no autopsy was conducted. *Burrage* illustrates the difficulty of making but-for cause determinations to a reasonable degree of medical certainty, even when an autopsy has been conducted and toxicology tested. In *Burrage*, a toxicologist determined a long-time drug user died from a "mixed drug intoxication" with heroin and other drugs playing a contributing role. *Burrage*, 571 U.S. at 207. Despite having detailed information about the level of each drug in the

decedent's system, neither the medical examiner nor the toxicologist could affirmatively state whether the decedent "would have lived if he had not taken the heroin" (the drug charged in the underlying offense). *Id.* In fact, despite expert testimony that "death would have been 'very less likely" absent the heroin, the Supreme Court determined that the government failed to establish heroin was the but-for cause of the death. Thus the question is not one of likelihood but of well-reasoned medical certainty. Reaching a conclusion on death without toxicology or an autopsy is not a well-reasoned medical certainty.

Here, absent any knowledge of what substances, or the levels of those substances that were in the decedents systems, determination of the but-for cause is virtually impossible. At best, Dr. Thomas could only speculate that the decedents conditions would have been less likely absent the drugs allegedly prescribed by Dr. Kraynak. However, like in *Burrage*, this statement is insufficient for Dr. Thomas to opine that the drugs were the but-for cause of any of the decedent's conditions and thereby renders his opinion speculative and inadmissible.

B. Dr. Thomas's opinion is not based on reliable principles and methods.

To be admissible Dr. Thomas' expert testimony must be "the product of reliable principles and methods." FED. R. EVID.702. Rule 702(c)'s use of the word "principles" refers to the theories the expert uses to explain facts. The word "methods" refers to how an expert derives these theories or opinions from the

facts. See 29 FED. PRAC. & PROC. EVID., Reliable Principles and Methods § 6268.1 (2d ed. 2019).

Dr. Thomas theorizes that Dr. Kraynak's medical treatment was "not in accordance with the accepted "treatment principles within the responsible segment of the medical community". He further opines that some of the decedents "would not have died" but for the prescription practices of Dr. Kraynak. Dr. Thomas comes to some of these conclusions even without autopsy or toxicology reports.

Absent a toxicology report, Dr. Thomas cannot determine whether the drugs in any one system was sufficient to cause serious bodily injury or whether other drugs or some unknown medical condition were the but-for cause of the injury. Further, Dr. Thomas failed to consider whether any of the patients had developed a degree of tolerance from their long-term use of pain relievers.

Dr. Thomas' opinions are based on inadequate documentation which precludes a true scientific conclusion. His methodology cannot be tested or peer-reviewed. There are no applicable error-rates, standards or controls. It is unlikely his conclusion would be accepted given the lack of information and the inherent difficulty of isolating but-for cause without toxicology or autopsies. Because the principles and methods Dr. Thomas utilized were so unreliable they cannot support an opinion on causation or that Dr. Kraynak's treatment of patients was outside the normal course of practice and had no legitimate medical pupose.

C. Dr. Thomas's opinion is not based on reliable application of principles and methods to the facts.

If an expert fails to reliably apply the proper principles and methods to the facts, the opinions derived therefrom can be called into question—regardless if the principles and methods themselves are reliable. *See* 29 FED. PRAC. & PROC. EVID., Reliable Application §6268.2 (2d ed. 2019).

For example, an expert does not reliably apply principles and methods to the facts where that expert unjustifiably extrapolates from an accepted premise to an unfounded conclusion. *Id.* (citing to *General Electric v. Joiner*, 522 U.S. 136, 146 (1997) (indicating there cannot be "too great of an analytical gap between data and the opinion")). Here, Dr. Thomas' opinion that the individuals died as a result of pain killers prescribed by Dr. Kraynak is based only on office and prescription records. Without autopsies or toxicology, Dr. Thomas can only guess about the controlled substances prescribed and whether they were medically legitimate.

Also, Dr. Thomas has failed to adequately account for alternative explanations. Some of the patients suffered from complicated medical conditions. Others had ongoing addiction problems that were interfering with the ability of Dr. Kraynak to properly treat them. It should also be noted that Dr. Thomas' opinion did not "grow naturally... out of research [he] conducted independent of litigation..." Rather, his conclusion was developed for the specific purpose of testifying. FED. R. EVID. 702 ACN (2000). He is the government's "go to" witness

in these cases. As a result, it is possible that Dr. Thomas was influenced by the number of deaths charged in the indictment and the resulting publicity. Dr. Thomas' unreliable application of the principles and methods necessary to make these determinations diminishes the reliability of his opinion on causation and whether Dr. Kraynak's treatments were outside the normal course of practice and had no legitimate medical purpose.

Conclusion

Dr. Thomas' opinions are based upon insufficient facts and data, unreliable principles and methods and the unreliable application of the principles and methods to the facts. As a result, Dr. Thomas' testimony does not meet Rule 702's reliability standards, and it is inadmissible to prove but-four causation required under 841(b)(1)(C)'s enhanced penalty provision or that Dr. Kraynak's treatments were outside the normal course of practice and had no legitimate medical purpose.

Respectfully submitted,

Date: March 24, 2020

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CERTIFICATE OF SERVICE

I, Thomas A. Thornton, Esquire, of the Federal Public Defender's Office, do hereby certify that I served a copy of the foregoing **Brief in Support of Motion to Exclude Expert Testimony**, via Electronic Case Filing, and/or by placing a copy in the United States mail, first class in Harrisburg, Pennsylvania, and/or by hand delivery, addressed to the following:

William Behe, Esquire Assistant United States Attorney

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Respectfully submitted,

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